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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,952	01/17/2002	Patricia S. Walker	D-2933CIP	2757

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,952	WALKER, PATRICIA S.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,10,12,36-39 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 10, 12, 36-39 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on October 3, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1-4, 10, 12, 36-39 and 43-45 are pending.

Applicant's amendment filed October 3, 2005 is acknowledged, and applicants' response has been fully considered. Claims 1, 36 and 45 have been amended. Therefore, claims 1-4, 10, 12, 36-39 and 43-45 are examined.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 10, 12, 36-39 and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "without treating hyperhydrosis of the human subject" in line 7-8. There is insufficient antecedent basis for this limitation in the claim, claim 1 does not recite the human subject has hyperhydrosis. See also claims 36 and 45. Claims 2-4, 10, 12, 37-39 and 43-44 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 10, 12, 36, 37 and 43-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)) and Slate *et al.* (U.S. 6,645,169, filed September 20, 2005). The response to applicants' argument is shown below.

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal dose of the toxin was injected into muscle at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 10, 12, 36 and 43-45). However, Borodic does not disclose the use of a needleless syringe.

Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (a needleless injection system; the whole document; claims 2 and 37); and Slate *et al.* teach there are three types of injections that may need to be performed by a needless injector: 1) shallow, intra-dermal injections, where the fluid medicament is infused into skin; 2) medium depth, subcutaneous injections where the fluid medicament is infused into fatty tissue beneath skin; and 3) deeper intra-muscular injections where the fluid medicament is delivered directly into muscle tissue, and depending on the type of injection that is desired and the general nature or condition of the patient's skin, the fluid

pressure that is necessary to make an appropriate hole can vary from injection to injection (column 1, lines 41-52; column 3, lines 8-63).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the three references to treat wrinkles and brow furrows by administering botulinum toxin A to muscles associated with brow furrows as taught by Borodic using a needleless injector as taught by Vadoud-Seyedi *et al.*, and the injector can have a sufficient pressure to deliver the medicament to the muscle tissue (deeper intra-muscular injection) as taught by Slate *et al.* because Vadoud-Seyedi *et al.* indicate the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, and suggest the injection of botulinum toxin with a Dermojet is an effective and comfortable technique (page 179, third and last paragraph); and Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-dermal, subcutaneous or intra-muscular). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. Since the botulinum toxin is administered to a muscle tissue associated to wrinkle or brow-furrow, it would not be expected the administration of botulinum toxin would also treat hyperhydrosis, where sweat glands are located in the dermal layer of the skin.

6. Claims 3, 4, 38 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic in view Vadoud-Seyedi *et al.* and Slate *et al.* as applied to claims 1, 2, 10, 12, 36, 37 and 43-45 above, further in view of McCabe *et al.* (U. S. Patent 5,525,510). The response to applicants' argument is shown below.

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal dose of the toxin was injected into muscle at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 10, 12, 36 and 43-45); Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (claims 2, 6, 37 and 40); Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-dermal, subcutaneous or intra-muscular), and the combined references teach the treatment of wrinkles and brow furrows by administering botulinum toxin A into muscle with a Dermojet having sufficient pressure to deliver the medicament to muscle tissue. However, Borodic, Vadoud-Seyedi *et al.* and Slate *et al.* do not disclose the use of a botulinum toxin coated onto the carrier.

McCabe *et al.* teach the biological material such as DNA, RNA, proteins or peptides is coated onto the carrier particles such as small gold beads or spheres (column 6, lines 22-35; claims 3, 4, 38 and 39).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art to combine the four references to treat wrinkles and brow furrows using the method taught by Borodic, Vadoud-Seyedi *et al.* and Slate *et al.* with botulinum toxin A coated onto the gold sphere taught by McCabe *et al.* because the treatment with neurotoxin coated onto the gold particle would be safer since the high density carrier with small particle size would readily enter

living cells without injuring the cells. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicant indicates the present claims recite the botulinum toxin is administered to a human subject using a needless syringe having a pressure sufficient to deliver the botulinum toxin to a muscle tissue associated with a wrinkle or brow furrow to reduce a muscle contraction of the muscle tissue without treating hyperhydrosis of the human subject; Vadoud-Seyedi *et al.* disclose needleless injection of a botulinum toxin into the sole of a pateint's foot to treat plantar hyperhydrosis, however, needleless injections of botulinum toxin into the palm to treat palmar hyperhidrosis is not recommended because of possible injury to superficial palmar nerves or vessels; combination of Borodic, Vadoud, and Slate references, as a whole, discloses needleless injection of a botulinum toxin may be effective in treating plantar hyperhydrosis, it fails to disclose, teach, or suggest all of the elements recited in the preaent claims; combination of the three references actually teaches away the claimed invention since the only reference discloses needleless injection of botulinum toxin (i.e., Vadoud) discloses administration of the botulinum toxin into the sole of a pateint's foot to treat plantar hyperhydrosis, where sweat glands are located in the dermal layer of the skin, while muscle tissue is located inwardly and away from the dermal layer. Furhtermore, a person of ordinary sklll in the art would not be motivated to use a needless injector to administer a botulinum toxin to a patient to treat a wrinkle or brow furrow because Vadoud specifically teaches that the sole of the foot is a special target region in which the nerves are located at deeper regions than other regions of the body, sueh as the palm of the hand. Thus, the sole of the foot represents a special adminietration site represented by a thick

layer of tissue covering the nerves. Other regions of the body where wrinkles and brow furrow occur, such as facial regions, do not have a thick layer of tissue covering nerves, and therefore, the benefits of treating plantar hyperhydrosis by needleleas injection of botulïnum toxin into the sole of the foot would not motivate a person of ordinary skill tn the art to use needleless injection to administer a botulinum toxïn to other (e. g., non-foot) regions of the body; regarding the rejection of claims 3, 4, 38 and 39 over Borodic in view of Vadoud-Seyedi *et al.* and Slate *et al.*, and further in view of McCabe *et al.*, McCabe fails to resolvethe deficiency of the combination of Borodic, Vadoud and Slate. The combination of the four references fails to disclose, teach or suggest all the elements recited in the claims (pages 6-11 of the response).

The response has been considered, however, the argument is not found persuasive because Boridic discloses the treatment of a wrinkle or brow furrows by administering a botulinum toxin using a syringe with a needle into muscles (column 5, lines 5-19); and the secondary reference, Vadoud-Seyedi *et al.* teach a technique of injection using needleless syringe (e.g., a Dermojet), which has advantages as compared to injection with needle, e.g., the technique is safer and the injection with pain level is acceptable. Although Vadoud-Seyedi *et al.* teach using botulinum toxin to treat plantar hyperhidrosis, which is a different condition from wrinkle or brow furrows, the reference does disclose the advantages of using a Dermojet to inject botulinum toxin in the treatment. Furthermore, the advantage of using needleless injector (e.g., less pain, no risk of infection-safer) is well known in the art and has been stated in Bellhouse's patents (e.g., US. Patent 5,899,880, column 1, lines 61-65), which are incorporated in their entirety by reference in the specification (page 23, lines 17-26); and Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-

dermal, subcutaneous or intra-muscular). Therefore, the motivation for a person of ordinary skill in the art to combine three references to inject a botulinum toxin with a needleless syringe for treating wrinkles and brow furrows is the advantage of using needleless injector, which is safer and less pain when compared to injection with a needle as indicated in Vadoud-Seyedi *et al.*, and an appropriate pressure of the injector can be applied if intra-muscular injection is needed as indicated by Slate *et al.* Thus, in the case of treating wrinkles and brow furrows, the first reference (i.e., Boridic) teaches the treatment of a wrinkle or brow furrows using a botulinum toxin, the second reference (Vadoud-Seyedi *et al.*) teaches the use of a needleless injector to administer botulinum toxin, and the third reference (Slate *et al.*) teaches a suitable pressure of an injector can be used for intra-muscular injection, which is the case for treating wrinkles and brow furrows. It appears applicants' response is based on the combination of Boridic and Vadoud-Seyedi *et al.*, not the combination of the three references. Regarding claims 3, 4, 38 and 39, McCabe *et al.* teach the biological material can be coated onto the carrier such as gold beads for needleless injection. Therefore, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
October 31, 2005